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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,920	09/30/2003	Christopher P. Knapp	279.640US1	2079

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
09/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,14-26,30-40,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14-26,30-40,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 14-26, 30-40, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claims 1, 16, and 35, the Examiner was unable to find support in the originally-filed disclosure for the combination of a first layer that leaves an uninsulated region and a second layer that is not adjacent to the surface of the electrode. Although support was found for "leaving a relatively small uninsulated region" of the first layer (page 5, lines 7-8) and a second layer that "at least partially covers the polymeric base coat" (page 5, line 23), the

Examiner was unable to find support for an electrode that leaves an uninsulated portion and has a second layer not adjacent to the surface of the electrode. For instance, the second layer could be adjacent the electrode over the uninsulated portion (*i.e.*, the second layer could cover the uninsulated portion). There is no support for leaving a certain area uninsulated and leaving that same certain area free of the second drug-eluting layer. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)). Similarly, claim 30 recites that the drug elution polymer layer is the inner layer leaving an uncoated portion and that the polymer barrier is adjacent the inner layer and not adjacent the surface of the electrode, but only the "polymer primer layer" has been disclosed as leaving an uninsulated region.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-11, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "a second layer adjacent the fist layer and not adjacent to the surface of the electrode including at least one pharmacological agent." It is unclear whether the first layer or the second layer includes

the pharmacological agent. The Examiner is considering the second layer to include the at least one pharmacological agent, but the claim should be clarified.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7, 9-11, 14-23, 25, 26, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (US 5,551,427, hereinafter "Altman"), or in the alternative under 35 U.S.C. 103(a) as being unpatentable in view of Altman and Bolz et al. (US 5,964,794, hereinafter "Bolz").

9. In regards to claims 1, 5, 9-11, 16, 21, 25, 26, and 30, Altman discloses a pulse generator (col. 11, lines 22-25); an electrical lead having a lead body and conductor (Fig. 9); and an electrode coupled to the conductor (Fig. 10), wherein the electrode includes a coating on at least a portion of the surface of the electrode, the coating including four or more layers (Fig. 16; the coating on the "portion of the electrode" is an arbitrary radially-projecting cylinder that passes through matrix (60) and at least two drug particles (156, 158, and 160) -- the claim language does not require that the coating cover any more than an arbitrarily small portion of the electrode, nor do the claims require anything more than arbitrary divisions between the coats/layers). Further, the first/inner layer of this coating includes an insulative polymer primer material (the matrix) while leaving an uninsulated region (Fig. 10 and col. 11, lines 38-40 -- all layers leave an uninsulated/uncoated region), the second layer (the region of the first drug particle in the arbitrarily small cylinder) is adjacent the first layer and not the electrode and includes at least one pharmacological agent, a third/outer layer (the region of the second drug particle in the arbitrarily small cylinder) includes at least one pharmacological agent/only a pharmaceutical agent (160), and a fourth porous polymeric layer (an arbitrary region of the cylinder containing drug and matrix) regulates the release of drug from the matrix (with respect to more inner regions -- col. 14, lines

11-14). The Examiner's position is that the claim language permits the differentiation between "layers" to be an arbitrary division because the layers, as claimed, do not necessarily *exclude* insulation, drug, or the combination of the two in any of the layers. Alternatively and additionally, Altman does not explicitly disclose that the radially-heterogeneous insulation and drug regions are four distinct "layers" applied in coats. However, Bolz teaches providing drug-eluting coatings to implantable electrodes in at least four distinct layers applied in coats (Fig. 8) to provide the predictable result of improved biocompatibility, drug release, and electrical characteristics (col. 1, lines 62-66 and col. 2, lines 1-25) with conventional coating techniques. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Altman's invention by providing the four drug-eluting coatings in layers to provide the predictable result of improved biocompatibility, drug release, and electrical characteristics with conventional coating techniques.

10. In regards to claims 2, 17, and 31, the electrode includes a helical tip (Fig. 10).

11. In regards to claims 3, 4, 6, 7, 14, 18-20, 22, and 23 the agent comprises an anti-arrhythmia agent (col. 6, lines 61-67). Claims 4, 7, 14, 19, 20, and 23 only limit the optional ("or") anti-inflammatory agent of the claim from which it depends, and Altman discloses an anti-arrhythmia agent. As such, an anti-arrhythmia agent still anticipates claims 4, 7, 14, 19, 20, and 23.

12. In regards to claim 15, the first layer increases the impedance of the electrode as it is an insulator (col. 10, line 28).

13. In regards to claim 33, the agent is an anti-inflammatory drug (col. 6, lines 65 and 66).

14. Claims 35, 36, 37, 39, 40, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman in view of Bolz.

15. In regards to claims 35, 39, 40, 44, and 45 Altman discloses the essential features of the claimed invention (as described above) including a first arbitrary layer/region comprising a polymeric base coat that does not coat a region of the electrode; a second arbitrary layer/region comprising a polymer and drug that at least partially coats the first layer and not the surface of the electrode (Figs. 10 and 16); a third arbitrary layer/region that comprises at least one drug and regulates the release by the second layer (as the drug must diffuse through this layer); and a fourth arbitrary layer/region between the second and third layers comprising a porous barrier (with respect to the more inner layers). Altman does not disclose that these layers/regions are coated sequentially, as claimed, by spraying. However, Bolz teaches that it is known to provide drug-eluting coatings, such as Altman's coating shown in Figures 10 and 16, to implantable electrodes in at least four distinct layers applied in coats (Fig. 8) by spraying (col. 7, line 42) to provide the predictable result of improved biocompatibility, drug release, and electrical characteristics (col. 1, lines 62-66 and col. 2, lines 1-25) with conventional coating techniques. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Altman's invention by providing the four drug-eluting coatings in layers by

spraying to provide the predictable result of improved biocompatibility, drug release, and electrical characteristics with conventional coating techniques.

16. In regards to claims 36 and 37, the agent comprises an anti-arrhythmia agent (col. 6, lines 61-67). Claim 37 only limits the optional ("or") anti-inflammatory agent of claim 36, and Altman discloses an anti-arrhythmia agent. As such, an anti-arrhythmia agent still anticipates claims 37.

17. Claims 8, 24, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (or Altman and Bolz), as applied to claims 5, 21, and 35 above, and further in view of Benz et al. (US 6,879,861, hereinafter "Benz"). Altman's (or Altman's modified) invention discloses the essential features of the claimed invention except for a base coat comprising EVOH. However, Benz teaches that it is known in the art to provide electrode insulation base coats comprising EVOH (col. 5, line 44) to provide the predictable result of an insulator more resistant to dielectric breakdown (title). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Altman's invention by providing an insulation base coat comprising EVOH to provide the predictable result of an insulator more resistant to dielectric breakdown.

18. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Altman (or Altman and Bolz), as applied to claim 30 above, and further in view of Casa-Bejar et al. (US 2002/0138123, hereinafter "Casa-Bejar"). Altman's (or Altman's modified)

invention discloses the essential features of the claimed invention except for an agent including an anti-proliferative drug. However, Casa-Bejar teaches that it is known in the art to provide agents including anti-proliferatives (par. 0005) to implantable devices to provide the predictable result of improving biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Altman's invention by providing an agent including an anti-proliferative to provide the predictable result of improving biocompatibility.

Response to Arguments

19. Applicant's arguments with respect to claims 1-11, 14-26, 30-40, 44, and 45 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762